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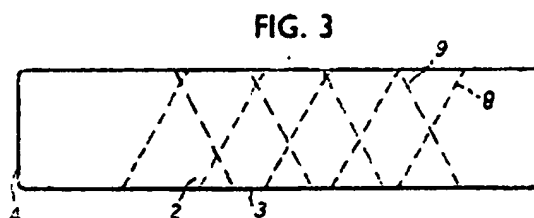
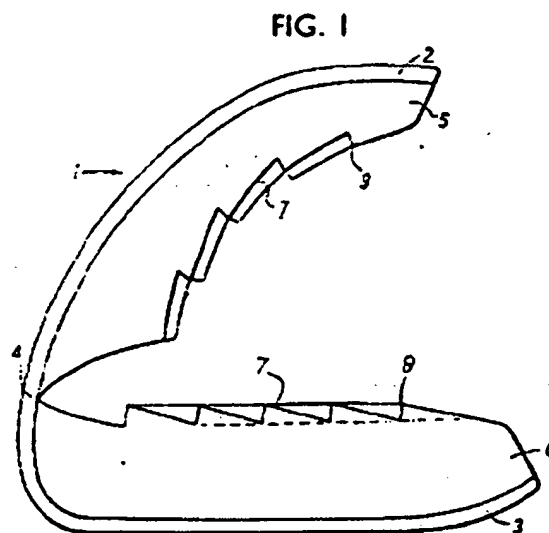
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SEXUAL STERILIZATION DEVICES

Patent number: GB1530282
Publication date: 1978-10-25
Inventor:
Applicant: FILSHIE G
Classification:
- international: F16B2/20
- european: A61F6/20C
Application number: GB19750030669 19750722
Priority number(s): GB19750030669 19750722

Abstract of GB1530282

1530282 Clips G M FILSHIE D
CASEY V HOUGHTON D F
HUBBACK and E M
NICHOLSON 10 Feb 1976 [12
Feb 1975 22 July 1975] 6042/75
and 30669/75 Heading E2B A
male or female sterilization
clamp com- prises a strip of
metal bent to form jaws 23 at
least one of which is provided
with a resiliently compressible
lining 5, 6 that is preferably
provided with a saw-tooth profile.
The teeth 8, 9 are arranged at an
oblique angle to the transverse
axis of the clamp and face
towards the clamp hinge area 4.
The teeth of the upper and lower
jaws slant in opposite directions
and intersect each other when
clamped together, (see Fig. 3).
The lining may be of silicone
rubber.



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PATENT SPECIFICATION

(11) 1 530 282

1 530 282

- (21) Application No. 6042/75 (22) Filed 12 Feb. 1975
 (21) Application No. 30669/75 (22) Filed 22 July 1975
 (23) Complete Specification filed 10 Feb. 1976
 (44) Complete Specification published 25 Oct. 1978
 (51) INT CL³ F16B 2/20
 (52) Index at acceptance E2B 4H



(54) IMPROVEMENTS IN SEXUAL STERILIZATION DEVICES

(71) We, GILBERT MARCUS FILSHIE, a British subject of 2 Pembroke Drive, Mapperley Park, Nottingham NG5 1PD, DONN CASEY, an Australian citizen of 141 Newmarket Road, Cambridge CB5 8HA, VERA, LADY HOUGHTON, a British subject of Becks Cottage, Whitehill Lane, Bletchingley, Redhill, Surrey RH1 4QS, DAVID FRANCIS HUBBACK, a British subject of 5 Mount Vernon, London NW3 and EDWARD MAX NICHOLSON, a British subject of 13 Upper Cheyne Row, London SW3, all being members of the SIMON POPULATION TRUST established by a Trust Deed dated 3rd April 1957; and GILBERT MARCUS FILSHIE, a British subject of 2 Pembroke Drive, Mapperley Park, Nottingham NG5 1PD, do hereby declare this invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to sexual sterilization devices in the form of a clip adapted to be clamped on a Fallopian tube or a vas deferens to effect occlusion thereof.

The requirements of ideal methods of both male and female sexual sterilization are that they should be simple, safe effective and reversible. Known methods fail to meet at least one of these requirements completely.

Methods of female sterilization such as salpingectomy and partial salpingectomy are safe and effective but are not considered reversible since in normal circumstances a minimum of two centimetres of Fallopian tube are removed and the resulting gap may reduce the chances of reversibility. Laparoscopic tubal diathermy is an effective method but is technically complex and occasionally fatal.

Two main types of female sterilization clip have been developed by others. Only one type is even reasonably satisfactory, however, and this has been designed specifically for use with the laparoscope.

This instrument is not felt to be practical in the Third World. If a clip applied to a Fallopian tube is to be completely effective it must maintain sufficient pressure to occlude the lumen despite any contraction of the tissue surrounding the lumen or any slight relaxation of the clip. Further, a clip needs a completely effective mechanism to prevent the tube slipping out. Known clips are either incapable of maintaining the necessary pressure, do not have a completely effective mechanism to prevent the tube slipping out, or are complicated to make or apply.

Hitherto, in male sterilization by vasectomy the normal method of performing the vasectomy has been to remove surgically a length of vas deferens, the two cut ends being ligated with suture material. Wire clips made of tantalum have been used instead of suture material but two and sometimes three clips have to be attached to each cut end of the vas deferens to ensure complete occlusion.

It is an object of this invention to provide an improved sexual sterilization device, applicable to both males and females, in the form of a clip adapted to be clamped on and thereby to occlude a duct through which gametes pass, such as a Fallopian tube or a vas deferens, which is simple, safe, effective and the application of which devitalizes a minimal length of duct.

Accordingly, the present invention consists in a sexual sterilization device in the form of a clip adapted to be clamped on and thereby to occlude a duct through which gametes pass, comprising a strip of metal bent to provide clamping jaws having opposing surfaces at least one of which is lined with a resiliently compressible material which is adapted to be in compression when the clip is clamped on a duct to effect occlusion thereof.

The device may be adapted either for use in sterilizing females by the occlusion of a Fallopian tube or for use in sterilizing males by the occlusion of a vas deferens.

Preferably, each of the opposing surfaces is lined with resilient material.

The resilient material is advantageously arranged to present to the duct a surface having a saw tooth profile in which the teeth face generally towards the interior of the clip.

Suitably, the metal is tantalum and the resilient material is silicone rubber, both of medical grade.

The invention will now be described by way of example with reference to the accompanying drawings in which:

Figure 1 is a side elevation of a sexual sterilization device according to the invention in the open position;

Figure 2 is a side elevation of the device of Figure 1 in the clamped position;

Figure 3 is a plan view of Figure 1; and

Figure 4 is an elevation of the device of Figure 1 in the open position, looking into the jaws.

Referring first to Figure 1, the clip 1 comprises a strip of tantalum which has been bent so as to form facing jaws 2 and 3 of about equal length formed in one at corresponding rear ends with a bight portion 4. The jaw 3 is substantially planar and meets the bight portion 4 at approximately right angles. The jaw 2 is concave toward the jaw 3. The forward ends of the jaws (spaced from the bight portion 4) are square ended; this is best seen in Figure 3.

The opposing faces of the jaws are lined with silicone rubber in the form of pads 5 and 6. The thickness of these pads is such that the silicone rubber is sufficiently compressed when the clip is first clamped on a Fallopian tube for the device to function in the manner to be described. The silicone rubber is suitably produced by thinning a silicone rubber adhesive of the kind known by Registered Trade Mark SILASTIC with a liquid silicone.

The interior faces of the silicone rubber pads, that is the faces spaced from the respective jaws, are shaped to give a saw tooth profile 7. The teeth extend diagonally across the width of the jaws and each has a first face substantially normal to the jaws and a second face which is inclined with respect to the jaws. The two faces meet in a line which forms the edge of the tooth and which is spaced at a maximum from the corresponding jaw. The teeth of each jaw are as shown in Figure 4 arranged in parallel lines with the teeth of one jaw inclined relatively to the teeth of the other jaw. This can be seen in Figure 3 where broken lines 8 represent teeth from the bottom jaw 3 and broken lines 9 from the top jaw 2. The second face of each tooth lies closer to the forward end of the corresponding jaw than does the first face of that tooth. Accord-

ingly, it will be understood that the teeth face "backwards" or generally towards the interior of the clip.

If the clip is to be applied to a female a strip of annealed tantalum of approximately 0.5mm thickness and 2.9mm width is used. If the tantalum is partially annealed the clip could be smaller in proportion.

To apply the clip to a female, it is first positioned so that the Fallopian tube lies perpendicular to and between the jaws. The jaws are then forced together with a scissors-like applicator, deforming the tantalum strip and so clamping the Fallopian tube between the jaws. The surface having a saw tooth profile which is presented to the Fallopian tube acts to prevent the Fallopian tube from slipping or being squeezed out of the clip. The clamping action causes a permanent deformation of the tantalum strip including an effective straightening of jaw 2 and a resilient compression of the silicone rubber as the Fallopian tube is squashed (see Figure 2). The clamping force is sufficient to ensure that the lumen of the Fallopian tube is flattened, and completely occluded.

The clip adapted to be applied to males is an approximately scaled-down version of the female clip. The male clip may be made somewhat narrower and shorter than the female clip especially if partially annealed tantalum is used, since this material is springier than annealed tantalum. In all other respects, however, the male clip is identical to the female clip.

In use of the clip in the performance of vasectomies, the scrotum is first cut to allow a section of the vas deferens to be pulled out, as hitherto has been the practice. The clip is then clamped to the exposed section of vas deferens, which is pushed back into place, the incision in the scrotum being sown up. It is expected that although the clip will in time cut through the vas deferens, the resilient lining which is a feature of this invention will slow down this cutting process sufficiently for the cut ends of the vas deferens to seal off naturally.

Subsequent to the application of the clips, one to each Fallopian tube or each vas deferens, the devitalized portion of each tube may tend to contract in a radial direction. The silicone rubber pads will then relax from their resiliently fully compressed state but still maintain pressure on the lumen of the tube and so ensure continued occlusion.

It will be seen that the possibility of the lumen of a Fallopian tube or vas deferens reopening after sterilization has taken place is considerably reduced by this invention.

A suitable method of construction, which lends itself to mass production, involves bending and shaping the tantalum strip to

the required form and then placing it in a mould the shape of which corresponds to the desired shape of the entire clip including the silicone rubber pads. The liquid silicone rubber is poured in and the pads are produced bonded to the tantalum, in one operation.

WHAT WE CLAIM IS:—

1. A sexual sterilization device in the form of a clip adapted to be clamped on and thereby to occlude a duct through which gametes pass, comprising a strip of metal bent to provide clamping jaws having opposing surfaces at least one of which is lined with a resiliently compressible material which is adapted to be in compression when the clip is clamped on a duct to effect occlusion thereof.

2. A sexual sterilization device as claimed in Claim 1 and adapted for use in sterilizing females by the occlusion of a Fallopian tube.

3. A sexual sterilization device as claimed in Claim 1 and adapted for use in sterilizing males by the occlusion of a vas deferens

4. A sexual sterilization device as claimed in Claim 2 or Claim 3, wherein each of the opposing surfaces is lined with resilient material.

5. A sexual sterilization device as claimed in Claim 4, wherein the resilient material is

arranged to present to the duct a surface having a saw tooth profile in which the teeth face generally towards the interior of the clip.

6. A sexual sterilization device as claimed in Claim 5, wherein the teeth of each jaw are arranged in parallel lines with the teeth of one jaw inclined relatively to the teeth of the other jaw.

7. A sexual sterilization device as claimed in any one of Claims 2 to 6, wherein the metal is tantalum and the resilient material is silicone rubber, both of medical grade.

8. A female sexual sterilization device, constructed, arranged and adapted to effect occlusion of a Fallopian tube substantially as hereinbefore described with reference to, and as shown in, the accompanying drawings.

9. A male sexual sterilization device, constructed, arranged and adapted to effect occlusion of a vas deferens substantially as hereinbefore described with reference to, and as shown in, the accompanying drawings.

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